SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1965

No. 824

ABBOTT LABORATORIES, ET AL., PETITIONERS,

vs.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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[fol. A]

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 15054, 15055

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMANN-LA ROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs.

APPEAL FROM THE JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Joint Appendix—Filed October 28, 1964

[File endorsement omitted]

[fol. 1]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

RELEVANT DOCKET ENTRIES

1.	9- 5-63	Complaint filed; Summons issued (exit papers to Marshal)..
2.	9- 5-63	Marshal returns on summons marked "Served 9-5-63".
3.	11- 5-63	Motion of defts to dismiss and for summary judgment, with Brief re same.
4.	11- 8-63	Cross Motion of Pltf for Summary Judgment.
5.	12-11-63	Memo of Pltf in support of Motion for Summary Judgment, and in opposition to deft's motion to dismiss & for summary judgment.
6.	1- 6-64	Reply Brief of Deft.
H.	1-13-64	Hearing Wright Ch. J. on cross-motions for summary judgment & deft motion to dismiss.
7.	1-15-64	Transcript of hearing Jan. 13, 1964.
8.	1-16-64	Reporter's notes of hearing on 1-13-64. 228 F. Supp. 855.
9.	4-30-64	Opinion Wright Ch. J.; Formal order to be submitted by counsel (Notice to counsel).
10.	5-15-64	Proposed form of judgment submitted by pltfs; June 10 Order Wright J. thereon.
11.	5-15-64	Proposed form of judgment submitted by defts.

[fol. 2]

	6-1-64	See Paper 10 for Judgment, Wright J. that pltfs American Home Products Corp., et al., Delaware corporations, and Pharmaceutical Manufacturers Association as representative of its member companies have standing to sue in this Court for the relief prayed in this action, and their Motion for Summary Judgment is granted; that Sections 1.104 (g)(1) and 1.105(b)(1) of the General Regulations, etc., issued by deft Commissioner of Food and Drugs, insofar as these sections require that the established name of a prescription drug must accompany each appearance of such drug's proprietary name or designation, are null and void and of no effect, and the statutory provisions on which they are based do not impose or authorize the defts to impose the requirements which they embody; enjoining defendants from enforcing, etc., said regulations; denying defendants' motion to dismiss and for summary judgment as to the plaintiffs named in paragraph (1) of the judgment; dismissing the complaint without prejudice as to the remaining plaintiffs for lack of proper venue, and that the respective parties shall bear their own costs of this action. (Notice to Counsel).
12.	7-29-64	Notice of appeal by certain pltfs.
13.	7-29-64	Bond of pltfs on appeal.
14.	7-29-64	Notice of appeal by defts (notice to clerk 3rd CCA and counsel).

[fol. 3]

IN THE UNITED STATES DISTRICT COURT

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF—Filed September 5, 1963

Plaintiffs, for their complaint herein, allege:

1. This is an action for a declaratory judgment that certain regulations promulgated by defendants are unauthorized by and contrary to law, and for injunctive and other relief.

2. The action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U. S. C. § 301, *et seq.* ("the Act"). This Court has jurisdiction pursuant to the provisions of 28 U. S. C. § 1331, 28 U. S. C. § 1337, 28 U. S. C. §§ 2201-02 and 5 U. S. C. § 1009. There exists between the parties an actual controversy, justiciable in character, in respect of which plaintiffs require a declaration of their rights by this Court. The amount in controversy between each plaintiff and the defendants exceeds $10,000, exclusive of interest and costs.

3. The plaintiffs herein are as follows:

Plaintiff	*State of Incorporation*	*Business Address*
Abbott Laboratories	Illinois	1400 Sheridan Road N. Chicago, Illinois
Alcon Laboratories, Inc.	Texas	6201 South Freeway Fort Worth, Texas
Allergan Pharmaceuticals	California	1000 S. Grand Avenue Santa Ana, California
American Cyanamid Company	Maine	859 Berdan Avenue Wayne, New Jersey
American Home Products Corporation	Delaware	685 Third Avenue New York, New York

Plaintiff	*State of Incorporation*	*Business Address*
Ames Company, Inc.	Indiana	819 McNaughton Avenue Elkhart, Indiana
Barnes-Hind Pharmaceuticals, Inc.	California	895 Kifer Road Sunnyvale, Calif.
Baxter Laboratories, Inc.	Delaware	6301 Lincoln Avenue Morton Grove, Ill.
[fol. 4]		
Brewer & Company, Inc.	Massachusetts	67 Union Street Worcester, Mass.
Burroughs Wellcome & Co. (U. S. A.), Inc.	New York	1 Scarsdale Road Tuckahoe, New York
Carter Products, Inc.	Maryland	2 Park Avenue New York, New York
Cutter Laboratories	Delaware	4th and Parker Streets Berkeley, California
The Dow Chemical Company	Delaware	1200 Madison Avenue Indianapolis, Ind.
Hoffman-LaRoche Inc.	New Jersey	340 Kingsland Street Nutley, New Jersey
Hynson, Westcott and Dunning Incorporated	Maryland	Charles & Chase Sts. Baltimore, Maryland
Johnson & Johnson	New Jersey	501 George Street New Brunswick, N. J.
Eli Lilly and Company	Indiana	740 South Alabama St, Indianapolis, Ind.
Mallinckrodt Chemical Works	Missouri	3600 N. Second St. St. Louis, Missouri
The S. E. Massengill Company	Tennessee	513-29 Fifth Street Bristol, Tennessee

Plaintiff	*State of Incorporation*	*Business Address*
Mead Johnson & Company	Indiana	2404 Pennsylvania Ave. Evansville, Indiana
Merck & Co., Inc.	New Jersey	126 East Lincoln Ave. Rahway, New Jersey
The Norwich Pharmacal Company	New York	17 Eaton Avenue Norwich, New York
Olin Mathieson Chemical Corporation	Virginia	745 Fifth Avenue New York, New York
Organon Inc.	New Jersey	375 Mt. Pleasant Ave. West Orange, N. J.
Parke, Davis & Company	Michigan	Jos. Campau at the River Detroit, Michigan
Chas. Pfizer & Co., Inc.	Delaware	235 East 42nd Street New York, New York
Philips Roxane, Inc.	Delaware	2400 Frederick Ave. St. Joseph, Missouri
A. H. Robins Company Incorporated	Virginia	1407 Cummings Drive Richmond, Virginia
Rowell Laboratories, Inc.	Minnesota	Baudette, Minnesota
[fol. 5]		
Schering Corporation	New Jersey	60 Orange Street Bloomfield, N. J.
G. D. Searle & Co.	Delaware	Searle Parkway Skokie, Illinois
Sherman Laboratories	(partnership)	5031 Grandy Avenue Detroit, Michigan
Smith Kline & French Laboratories	Pennsylvania	1500 Spring Garden St. Philadelphia, Penna.

Plaintiff	*State of Incorporation*	*Business Address*
Sterling Drug, Inc.	Delaware	1450 Broadway New York, New York
The Upjohn Company	Delaware	7000 Portage Road Kalamazoo, Michigan
Vale Chemical Company, Inc.	Delaware	1201 Liberty Street Allentown, Penna.
Warner-Lambert Pharmaceutical Company	Delaware	201 Tabor Road Morris Plains, N. J.
Pharmaceutical Manufacturers Association	Delaware (non-profit membership association)	1411 K Street, N. W. Washington, D. C.

The plaintiffs other than Pharmaceutical Manufacturers Association ("PMA") are hereinafter collectively referred to as "plaintiff companies."

4. Each of the plaintiff companies is engaged in the manufacture, and distribution in interstate commerce, of drugs, as that term is defined in Section 201(g) of the Act, 52 Stat. 1041 (1938), 21 U. S. C. § 321(g), and, more particularly, of drugs subject to the requirements of Section 503(b)(1) of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 353(b)(1), more commonly known as "prescription drugs."

5. PMA's membership includes about 140 member companies which are engaged in the manufacture of prescription drugs and which are believed to produce in excess of 90 per cent of the nation's total production of such drugs. The plaintiff companies are all members of PMA.

[fol. 6] 6. The defendant Anthony J. Celebrezze is the Secretary of the Department of Health, Education and Wel-

fare ("the Secretary"), who is charged with the administration of the Act. The defendant George P. Larrick is the Commissioner of Food and Drugs ("the Commissioner"), to whom the Secretary had delegated this authority. 22 Fed. Reg. 1051, as amended, 25 Fed. Reg. 8625. Each of the defendants is a resident of the District of Columbia.

7. The prescription drugs distributed by plaintiff companies in interstate commerce are not distributed directly to the patients who use these drugs. Rather, prescription drugs are distributed by plaintiff companies, or by their vendees, to physicians or other practitioners licensed by law (hereinafter "physicians"), to institutions, such as hospitals and clinics, in which the dispensing of prescription drugs is supervised by physicians, and to pharmacists, who in turn dispense those drugs to patients. No pharmacist or hospital or clinic may lawfully dispense prescription drugs to patients except upon the prescription or other direction of a physician. Accordingly, patients may lawfully obtain prescription drugs only from or pursuant to the direction of, and hence only under the supervision of, a physician.

8. In connection with its distribution of prescription drugs in interstate commerce each of the plaintiff companies prepares and distributes large quantities of labels, labeling material (such as product brochures) and advertising matter (such as advertisements in medical journals). Because, as set forth above, prescription drugs may be dispensed to patients only by or under the direction of a physician, labels, labeling and advertising matter for those drugs are not directed to the general public but rather to physicians, by plaintiff companies' professional service representatives, through the mails, in professional medical publications and the like, and, to some extent as in the case of material inserted in the drug's package, to the dispensing pharmacist, hospital or clinic. At all times each plain-
[fol. 7] tiff company has on hand and on order large quan-

tities of labels, other labeling material and advertising matter, prepared and printed at substantial expense, to be used in the future distribution of the prescription drugs which it manufactures.

9. The distribution by plaintiff companies of certain of the materials referred to in paragraph 8 is required by Federal law and regulations issued by the Commissioner and the distribution of the other materials there referred to is necessary or useful in the conduct of plaintiff companies' businesses.

10. There exists between the parties an actual controversy, justiciable in character, as to whether plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure and condemnation of their drugs, and injunctive actions, continue to distribute labels, other labeling material and advertising matter in which the established name, as defined below, of a prescription drug does not accompany every appearance of that drug's proprietary name, including labels, other labeling material and advertising matter printed and prepared at substantial expense and now in plaintiff companies' possession or subject to their control or now being ordered for subsequent distribution. The defendants, through formal and purportedly final and effective regulations, have taken the position that this material may not be distributed because it does not contain a statement of the established name of a prescription drug accompanying every appearance of that drug's proprietary name. Plaintiff companies believe that the defendants have no legal right to require such repetition of the established name and that such repetition will serve no useful purpose, will render the material less readable, and will impair the value of such material to plaintiff companies in the conduct of their businesses. The controversy turns upon the legal validity of these regulations, recently issued by the Commissioner, which regulations operate to prevent plaintiff companies from continuing their [fol. 8] present method of operating their businesses and to

interfere with mutually advantageous relationships which plaintiff companies have maintained with physicians and other persons. The genesis of said controversy is set forth below.

11. In accordance with conventional commercial practices and the trademark laws of the United States, proprietary, or brand, names are usually assigned by each plaintiff company to the prescription drugs which it distributes. The proprietary, or brand, name, which appears on the labels, and in the labeling and advertising, of the particular prescription drug, serves to identify the source of that drug. Said name serves the further function of distinguishing the drug from drugs with active ingredients of the same or similar chemical composition manufactured by other companies, including other plaintiff companies so that physicians may, if they wish to do so, when prescribing for patients, readily and conveniently express a preference among the sources from which such drugs are available by designating a drug by brand name. Since drugs with active ingredients of the same or similar chemical composition can and do differ in their therapeutic effect by reason of differences in binders and other inactive ingredients, and quality and methods of manufacture, the ability to distinguish between different brands of drugs with the same or similar active ingredients is important to physicians and to plaintiff companies in the conduct of their businesses.

12. Most prescription drugs can also be identified by a non-proprietary name. Such a non-proprietary name, often called "generic name," may be a "systematic chemical name," a "common or usual name," an "official title" used or adopted for use in an "official compendium" (United States Pharmacopeia, Homeopathic Pharmacopoeia, or National Formulary), or an "official name" designated by the Secretary under Section 508 of the Act, added by Section 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358. Under Section 502(e)(2) of the Act, added by Section 112(a) of the Drug Amendments of 1962, 76 Stat.

[fol. 9] 790, 21 U. S. C. § 352(e)(2), the term "established name" is defined as "(A) the applicable official name designated pursuant to Section 508, or (B), if there is no such name * * * the official title thereof in [an official] * * * compendium, or (C) if neither clause (A) nor clause (B) * * * applies, then the common or usual name * * * ." A single established name may be, and often is, the applicable established name for two or more prescription drugs distributed by different companies under different proprietary names.

13. Section 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), provides that the label and labeling of a prescription drug shall cause that drug to be "misbranded" unless:

> "The established name of such drug * * * on such label (and on any labeling on which a name for such drug * * * is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug * * * ."

14. Section 502(n) of the Act, added by Section 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U. S. C. § 352(n), provides that a prescription drug shall be deemed to be "misbranded" if the advertising for such drug does not contain:

> "A true statement of * * * the established name * * * printed prominently and in type at least half as large as that used for any trade or brand name thereof * * * ."

15. The introduction into interstate commerce of a "misbranded" drug and the "misbranding" of any drug in interstate commerce are declared unlawful by Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), 21 U. S. C. §§ 331 (a) and (b). The introduction into interstate commerce of a prescription drug alleged to be misbranded or the alleged misbranding of a drug in interstate commerce may

result in the institution of (a) one or more seizure proceedings under which said drugs are sought to be condemned and forfeited, (b) an injunction proceeding, or (c) [fol. 10] criminal prosecution of the person or persons causing such introduction into interstate commerce. In a business such as that of the plaintiff companies, which depends heavily on the trust and confidence of physicians and the general public, the mere institution of any such action, regardless of its eventual outcome, can have serious financial and other consequences on the defendant thereto, since a large proportion of the general public and of physicians interpret the institution of any such action as reflecting adversely upon the effectiveness and purity of the drugs involved and the reputation of the manufacturer even if such action alleges no deficiency in the purity, safety, potency or effectiveness of the product. The consequences of a successful criminal prosecution or seizure proceeding are additionally severe in that such a criminal prosecution may result in a fine of $1,000.00 or a jail term of one year, or both, and such a seizure proceeding in the forfeiture of thousands of dollars worth of valuable drugs.

16. On February 14, 1963, the defendant Commissioner proposed the adoption of certain new general regulations under the Act. 28 Fed. Reg. 1448-49. With respect to prescription drugs, the proposed regulations required, *inter alia*, that on each label, and each piece of labeling and advertising, for a prescription drug bearing a proprietary name:

> "The established name, if such there be, corresponding to such proprietary name or designation, *shall* accompany *each* appearance of such proprietary name or designation. The established name *shall* appear in immediate conjunction with the proprietary name or designation, without intervening matter except the words 'brand of' or, alternatively, brackets surrounding the established name." (Emphasis supplied.)

17. Plaintiff companies believed that these proposed regulations were inconsistent with and went beyond the requirements of the statute, that the value of plaintiff com- [fol. 11] panies' labels, labeling and advertising would be impaired were this material to contain the statements to be required under the proposed regulations, and that the proposed regulations were in derogation of the basic statutory purpose. Plaintiff companies therefore individually or through PMA objected to the proposed requirement that the established name of a prescription drug accompany each mention of any proprietary or brand designation for that drug.

18. On June 20, 1963, the Commissioner promulgated final regulations. 28 Fed. Reg. 6375. These regulations recited that they were effective on publication. *Id.* at 6377. They contain in pertinent part a requirement that on the labels and in labeling and advertising of prescription drugs having an established name the established name not only must appear prominently and in letters at least half as large as the letters comprising the proprietary or brand name, but that also:

> "The established name, if such there be, corresponding to such proprietary name or designation, *shall* accompany *each* appearance of such proprietary name or designation. The established name *shall* be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name *shall* be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name." Regulations, §§ 1.104(g)-(1), 1.105(b)(1). (Emphasis supplied.)

19. The regulations are written in mandatory terms and apply to all labels, labeling, and advertising used by plaintiff companies for their prescription drugs. Section 1.105(k) of the regulations provides that the issuance of a

drug advertisement not in compliance with Section 502(n) of the Act "and the applicable regulations thereunder shall cause stocks of such drugs in possession of the person [fol. 12] responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded * * * ." The adoption and promulgation of the regulations impose a duty upon the defendants to enforce and to cause enforcement of the statute in accordance with the terms of such regulations.

20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants' statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. No provision of the Act requires, or authorizes the defendants to require, that a drug's established name accompany every appearance of that drug's proprietary name.

21. As heretofore recited, prescription drugs are dispensed to patients only under the supervision of physicians and accordingly the labels, labeling and advertising of prescription drugs are directed to physicians rather than patients. By virtue of their training and experience physicians are well aware that prescription drugs with active ingredients of comparable chemical composition are manufactured and distributed by different manufacturers, including different plaintiff companies, under different proprietary or brand names, and are well aware that the proprietary name of a prescription drug is a designation of its source and serves to differentiate that drug from drugs with active ingredients of the same or similar chemical composition distributed by other companies. So long as the established name of a prescription drug appears prominently on the label and in the labeling and advertising of that drug, and in type at least half as large as that used

for that drug's proprietary name, physicians are advised of the active ingredients of that drug and do not require repetition of the established name with each mention of [fol. 13] the proprietary name to realize the nature, type or composition of such drug.

22. In order that labels, labeling and advertising may perform their respective functions it is necessary that they be read by physicians. It is, therefore, of importance to physicians, their patients and plaintiff companies that the information contained on their labels, labeling and advertising be presented in an intelligible and readable manner. The aforesaid regulations, however, would cause labels, labeling and advertising to become confusing and repetitious and more difficult for physicians to read and understand than are plaintiff companies' present labels, labeling and advertising, while containing no more information than that contained in plaintiff companies' present labels, labeling and advertising.

23. As heretofore recited, prescription drugs having the same established name but different proprietary names can and do differ in their therapeutic effect. It is, therefore, fallacious to equate drugs with different proprietary names but the same established name, and the Congress had no intention of so doing. The regulations, however, by requiring a drug's established name to accompany in close conjunction every appearance of that drug's proprietary name, lead to the erroneous conclusion, detrimental to plaintiff companies' businesses and to patients, that drugs with the same established name are always and in all respects identical.

24. The effect of the aforesaid regulations, unless this Court enters a decree declaring that such regulations are unwarranted, unauthorized and unlawful, is to require plaintiff companies, in order to avoid criminal prosecution, seizure proceedings and injunctive actions, to cease the distribution of labels, other labeling material and adver-

tising matter (including boxes, brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogues, house organs and print advertisements) in the same form [fol. 14] as heretofore distributed by plaintiff companies, including varying amounts of such materials now in their possession or subject to their control or on order. Some plaintiff companies are required by such regulations to revise and reprint at substantial expense such material now in their possession or subject to their control or on order, even though, as required by statute, the established name of the drug already appears on each document prominently and in type at least half as large as that used for any proprietary name. Further, the use of labels, other labeling material and advertising matter which comply with the regulations will impair the value to all plaintiff companies of these materials and injure plaintiff companies in their businesses.

25. Plaintiffs have exhausted all administrative remedies open to them, and have no prompt, adequate and effective remedy at law, and the present action is the only means available to them for the protection of their rights.

Wherefore, plaintiffs pray that this Court

(1) issue a judgment declaring that Sections 1.104-(g)(1) and 1.105(b)(1) of the General Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 28 Fed. Reg. 6375 (June 20, 1963), issued by the Commissioner purporting to act under authority delegated to him by the Secretary, are null and void and of no effect, and that the statutory provisions on which they purportedly are based do not impose, or authorize the defendants to impose, the requirements which they embody;

(2) enjoin and restrain the defendants and all persons acting under their direction and authority, or in active concert or participation with them, from enforcing or causing to be enforced, or from attempting to enforce or to

cause to be enforced, by any administrative action or civil or criminal proceeding, the requirements of such regulations; and,

[fol. 15] (3) grant such other or further relief as may be appropriate.

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[fol. 16]

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[fol. 17]

IN THE UNITED STATES DISTRICT COURT

MOTION TO DISMISS AND FOR SUMMARY JUDGMENT OF DISMISSAL—Filed November 5, 1963

I.

Come now the defendants, Anthony J. Celebrezze, Secretary of Health, Education, and Welfare, and George P. Larrick, Commissioner of Food and Drugs, and pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, move

the Court to dismiss the complaint for declaratory judgment and injunctive relief filed herein for the following reasons and on the following grounds:

A. To dismiss the Pharmaceutical Manufacturers Association as a plaintiff as the Association lacks capacity to sue since there is no case or controversy between the Association and defendants.

B. To dismiss the following corporations as plaintiffs as the venue of this Court is improper, in that said plaintiff corporations are not residents of the State of Delaware as required by 28 U. S. C. 1391, and in that the Complaint affirmatively states that the firms are incorporated in States other than Delaware:

Abbott Laboratories—State of Illinois [Complaint, ¶ 3, p. 1]

Alcon Laboratories, Inc.—State of Texas [Complaint, ¶ 3, p. 1]

Allergan Pharmaceuticals—State of California [Complaint, ¶ 3, p. 1]

American Cyanamid Company—State of Maine [Complaint, ¶ 3, p. 1]

Ames Company, Inc.—State of Indiana [Complaint, ¶ 3, p. 1]

Barnes-Hind Pharmaceuticals, Inc.—State of California [Complaint, ¶ 3, p. 2]

[fol. 18] Brewer & Company, Inc.—Commonwealth of Massachusetts [Complaint, ¶ 3, p. 2]

Burroughs Wellcome & Co. (U. S. A.) Inc.—State of New York [Complaint, ¶ 3, p. 2]

Carter Products, Inc.—State of Maryland [Complaint, ¶ 3, p. 2]

Hoffman-LaRoche, Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

Hynson, Westcott and Dunning Incorporated—State of Maryland [Complaint, ¶ 3, p. 2]

Johnson & Johnson—State of New Jersey [Complaint, ¶ 3, p. 2]

Eli Lilly and Company—State of Indiana [Complaint, ¶ 3, p. 2]

Mallinckrodt Chemical Works—State of Missouri [Complaint, ¶ 3, p. 2]

The S. E. Massengill Company—State of Tennessee [Complaint, ¶ 3, p. 2]

Mead Johnson & Company—State of Indiana [Complaint, ¶ 3, p. 2]

Merck & Co., Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

The Norwich Pharmacal Company—State of New York [Complaint, ¶ 3, p. 2]

Olin Mathieson Chemical Corporation—Commonwealth of Virginia [Complaint, ¶ 3, p. 2]

Organon Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

Parke, Davis & Company—State of Michigan [Complaint, ¶ 3, p. 2]

A. H. Robins Company, Incorporated—Commonwealth of Virginia [Complaint, ¶ 3, p. 3]

[fol. 19] Rowell Laboratories, Inc.—State of Minnesota [Complaint, ¶ 3, p. 3]

Schering Corporation—State of New Jersey [Complaint, ¶ 3, p. 3]

Sherman Laboratories—partnership—business address: Detroit, Michigan [Complaint, ¶ 3, p. 3]

Smith Kline & French Laboratories—Commonwealth of Pennsylvania [Complaint, ¶ 3, p. 3]

C. To dismiss the action in its entirety as this Court is without jurisdiction to entertain this suit because the

complaint fails to allege a case of actual controversy within the meaning of the Declaratory Judgments Act.

D. To dismiss the action in its entirety as the complaint fails to join an indispensable party, the Attorney General of the United States.

E. To dismiss the action in its entirety as the complaint fails to allege sufficient facts to state a claim appropriate for the exercise of the Court's discretion under the Declaratory Judgments Act. A regulation which interprets a portion of the Federal Food, Drug, and Cosmetic Act is not sufficient to support a suit for a Declaratory Judgment. Further, plaintiffs have not alleged facts which indicate that there has been any threat of enforcement with respect to plaintiffs.

F. The Court is without jurisdiction to entertain this suit because it is in substance and effect a suit against the United States to which it has not consented.

II.

The defendants further move the Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, to grant summary judgment of dismissal in favor of the defendants on the grounds that there is no genuine issue as to any material fact which precludes relief to the defendants, and [fol. 20] that defendants are entitled to judgment as a matter of law, since the regulations in question are reasonable, are in accordance with the clearly expressed intention of the Congress, and carry out the purpose of the statute.

Respectfully submitted,

Alexander Greenfeld, United States Attorney, Wilmington, Delaware.

William W. Goodrich, Assistant General Counsel for Food and Drugs.

Joanne S. Sisk, Nancy N. Keefe, Attorneys, United States Department of Health, Education and Welfare, Washington, D. C. 20201.

[fol. 21]

IN THE UNITED STATES DISTRICT COURT

PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT—
Filed November 8, 1963

Each of the plaintiffs separately opposes both defendants' motion to dismiss and defendants' motion for summary judgment and cross-moves the Court on the papers filed in this proceeding for summary judgment under Rule 56 of the Federal Rules of Civil Procedure on the ground that there is no genuine issue as to any material fact and that plaintiffs are entitled to judgment as a matter of law.

Alexander L. Nichols, William S. Megonigal, Jr., 3000 DuPont Building, Wilmington 1, Delaware, Attorneys for Plaintiffs.

Of Counsel:

Morris, Nichols, Arsht & Tunnell, 3000 DuPont Building, Wilmington 1, Delaware.

Gerhard A. Gesell, Stanley L. Temko, Herbert Dym, 701 Union Trust Building, Washington 5, D. C., Attorneys for Abbott Laboratories; Alcon Laboratories, Inc.; Allergan Pharmaceuticals; American Cyanamid Company; American Home Products Corporation; Ames Company, Inc.; Barnes-Hind Pharmaceuticals, Inc.; Baxter Laboratories, Inc.; Brewer & Company, Inc.; Burroughs Wellcome & Co. (U. S. A.) Inc.; Carter Products, Inc.; Cutter Laboratories; The Dow Chemical Company; Hoffman-LaRoche Inc.; Hynson, Wescott and Dunning, Incorporated; Johnson & Johnson; Eli Lilly and Company; Mallinckrodt Chemical Works; The S. E. Massengill Company; Mead Johnson & Company; The Norwich Pharmacal Company; Olin Mathieson Chemical Corporation; Organon Inc.; Parke, Davis & Company; Chas. Pfizer & Co., Inc.; Philips Roxane, Inc.; A. H. Robins Company, In-

corporated; Rowell Laboratories, Inc.; Schering Corporation; G. D. Searle & Co.; Sherman Laboratories; Smith Kline & French Laboratories; Sterling Drug, Inc.; The Upjohn Company; Vale Chemical Company, Inc.; Warner-Lambert Pharmaceutical Company.

Of Counsel:

Covington & Burling, 701 Union Trust Bldg., Washington 5, D. C.

[fol. 22] Hayward H. Coburn, 1100 Philadelphia National Bank Building, Broad and Chestnut Streets, Philadelphia 7, Pennsylvania, Attorney for Merck & Co., Inc.

Of Counsel:

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Lloyd N. Cutler, Marshall Hornblower, 815—17th Street, N. W., Washington 6, D. C.; C. Joseph Stetler, Vice President and General Counsel, John K. Worley, Assistant General Counsel, Pharmaceutical Manufacturers Association, 1411 K Street, N. W., Washington 5, D. C., Attorneys for Pharmaceutical Manufacturers Association.

Of Counsel:

Wilmer, Cutler & Pickering, 815—17th Street, N. W., Washington 6, D. C.

November 8, 1963.

[fol. 23]

IN THE UNITED STATES DISTRICT COURT

Excerpts From the Transcript of the Oral Argument —January 13, 1964

Wilmington, Delaware

Before: Hon. Caleb M. Wright, Chief Judge.

APPEARANCES

For the Plaintiffs:

Alexander L. Nichols, Esq., and William S. Megonigal, Jr., Esq., of Morris, Nichols, Arsht & Tunnell;

Gerhard A. Gesell, Esq., Stanley L. Temko, Esq., and Herbert Dym, Esq., of Covington & Burling, Washington, D. C.;

Hayward H. Coburn, Esq., of Drinker, Biddle & Reath, of Philadelphia, Pa.;

Lloyd N. Cutler, Esq., and Marshall Hornblower, Esq., of Wilmer, Cutler & Pickering, of Washington, D. C.;

John K. Worley, Esq., of Washington, D. C.

For the Defendants:

Alexander Greenfeld, Esq., U. S. Attorney, and William J. Wier, Esq., Asst. U. S. Attorney;

William W. Goodrich, Esq., Asst. General Counsel for Food and Drugs.

COLLOQUY BETWEEN COURT AND COUNSEL

Mr. Goodrich: • • • If these procedural matters are not adequate to dismiss, then, of course, we defend the [fol. 24] regulations on their merits and contend that they are plainly authorized by the law to carry out the evident intent of the Congress and should be sustained.

• • • • • • •

The Court: Mr. Goodrich, when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.

Mr. Goodrich: We do indeed, sir.

The Court: If not, you take whatever steps are necessary to enforce them.

Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here.

• • • • • • •

We have here a case in which the Congress' attention has been sharply focused on this very issue and it has settled it. Under the gambling device case from Justice Jackson, which we have cited in our brief, this is entitled to a very strong presumption.

The Court: Let me get this straight now. The sharp focus which you are referring to is based upon two things, is it not: The rejection of the O'Brien amendment and the statement of Senator Kefauver when he was making the report of the joint—

Mr. Goodrich: I go back also, your Honor, to the first Senate report in August. There was a July report of the [fol. 25] first Senate bill. Then the second report after the President's call for strengthening of the bill originally reported out by Senator Eastland's group.

The Court: What is there in the first Senate report?

Mr. Goodrich: "Wherever". The same language that wherever the trade name is used the generic name should be used.

The Court: That is what we are trying to do, to figure out what the "wherever" means.

Mr. Goodrich: Yes, sir.

The Court: And the only place we can find that—I mean you have to base it upon the failure to adopt the O'Brien amendment and the statement of Senator Kefauver in making the report; isn't that true?

Mr. Goodrich: I think the other report is very significant, because it uses the same language that Senator Kefauver later used to explain what was meant by "wherever".

The Court: Is there anything in the report where it says, "We intend that every time the brand name is used the generic or established name shall follow"?

Mr. Goodrich: Only the word "wherever". "Wherever" is explained—the statutory language is in it and the word used in the first report on S-1152, part 2, is that "any" means "wherever", and this was then cut back by the O'Brien amendment, and then went to conference, and Senator Kefauver came back with the identical language that was in the original S-1152 that was reported out in August, [fol. 26] and this is the contention that we have on the legislative history.

The Court: Go ahead. Don't let me stop you.

Mr. Goodrich: I have concluded. I thought you might have another question, your Honor.

The Court: I was trying to find this.

Mr. Goodrich: You will find this on page 8 of the second part of the Senate report 1744. Here is the language: "It would also require that on the labels and any labeling, wherever a trade or brand name is used, the established name as defined in this section must be shown in type at least half as large as that used for any trade or brand name." This part of the report, your Honor, follows the bill and is in the debate in the Senate right at the first part of the compilation. Thank you, your Honor.

The Court: Thank you.

Mr. Gesell: If the Court please, I think the best starting point is to start at the point where Mr. Goodrich started. This is not a question of trying to win in a courtroom something that was lost in the Congress any more than it is a question of the FDA trying to prevail in a court on an issue that they would have liked to have seen Congress decide in their favor in the legislative history. I think it is not helpful to present this case except in these terms: A major

industrial problem of transcendant consequence cutting across all of the companies is presented here, and we are not trying to tell the agency how to administer the Act, as Mr. Goodrich suggests. We are asking your Honor to tell them that they cannot exceed the authority that was given them by the Congress. They can administer the Act any way they please within the authority that they have, but they cannot exceed that authority.

The specific issue here is whether they are not exceeding that authority in saying that we must on every adver- [fol. 27] tisement of a prescription drug, on every label and every price list and every box, every mailing piece, every carton, every bit of literature that we have, every time we use our trade name also present the information as to the generic name. We say Congress did not require that; that the statute does not direct them to do that; that their command is a command beyond the scope of the statute; and that they are acting illegally; and we have come here as an industry to get that issue resolved. We are not asking in any way for an abstract opinion. We are asking to be relieved of the burden of an unauthorized action by the agency in the administration of the statute, and that is our right, as I intend to show.

The impact of this regulation is a very real one. It affects the manner in which all of these companies must order their affairs. It affects a multitude—I don't know whether one could estimate it, but certainly in the hundreds of thousands of different pieces of literature that are printed and reprinted daily. It affects thousands of drugs, and this industry is entitled and these plaintiffs I represent are entitled to have that determined. This is not as though Mr. Goodrich had made some kind of a speech to some kind of group of drug people or answered some kind of a casual letter, both of which he does quite frequently. This is entitled "A Regulation for the Enforcement of the Act." It is published in the Federal Register and it tells each of my clients and all the other drug companies that what they are doing is illegal; that their drugs can be seized and kept off

the market because they are doing it; that their officers can go to jail because the companies are doing it; that we are subject to injunction; and, as Mr. Goodrich says, that we stand and confront the possibility of the administrative operation by the agency itself not only in its referrals to the Attorney General, but in its handling of new drug applications. We are confronted with something very real.

[fol. 28] The Court: Would you call it "jeopardy"?

Mr. Gesell: I think the words that the cases use are "at peril" or "at risk". "Jeopardy" would be equally good. We are, and we are daily in it, and it seems to me that the impact of this regulation is obviously immediate and obviously real, and to get the flavor from the brief and, I must say, from the argument today that all they have done is to try to help us out by giving us a little old interpretation, and that maybe sometime in connection with some drug somewhere at their own choosing, their own forum, their own place, their own opportunity, they might bring a case, criminal, civil, or what not, is to understate what has happened. Surely they mean this regulation. Surely when they put it out and say this is what you shall do—not what you could do to live up to the statute, not what we think would be best for you to do, not one possibility, but you shall do it, and they put it out as an enforcement regulation, we have got a practical problem as businessmen that we have to get some relief on. Now, if the statute is held to mean what Mr. Goodrich says, these companies will comply with it. But they should not be required to comply with a directive of this character which is beyond the authority that they have from the statute.

In the main that is why we are here. We think the risks are immediate. We think they are very real. The agency is going to enforce this statute obviously in the manner they say, and we feel that we are entitled to come here for relief.

* * * * * * *

Now, on the question of the merits, if your Honor please, I think we ought to have the provision in front of us. It is at 3a, printed in the appendix of our brief.

Now, the Food & Drug Administration says that this section requires this regulation, that they have no choice, [fol. 29] that this says to them, it must be every time. They are explicit on that at page 33 of their brief. And I would simply say that a reading of it just in the normal manner that anyone would read it can't possibly pull from it that meaning. The ambiguity that he seeks to create in order to psychoanalyze these different Congressmen just isn't there. This is a straightforward statement of what Congress said, and it is just as clear. It says that you must print the generic name prominently and you must print it in type at least half as large. But it doesn't say "every time".

We are not dealing, your Honor, with a very abstruse concept. I think Congressmen would understand that if they meant every time, they could say "every time", And if they had said "every time", I call your Honor's attention to the fact that they would not have needed to say "prominently" at all. They have specified that the type must be half the size. What is the point of "prominently" in the statute if it was an "every time" statute? This simply directs clearly that you must print the generic name. It gives the size of type, and they say it must be prominent. But it does not say in its four corners in any way "every time".

We don't see the ambiguity that necessitates the legislative hunt, which I am going to go through with you and give you our view on phases of it. For an officer of the Government to stand up and say that that is a direction to him to require every label and, on the related provision of the next page, every ad to show this "every time" is to assume that the Congressmen didn't use the simplest, most ordinary and most natural English to express the simplest, most ordinary idea.

We are not concerned with some abstruse field of law. We are not concerned with possible misunderstandings [fol. 30] about the intricacies in the Congress. I cannot con-

ceive of any Congressman not saying, "Well, if it is to be every time, why don't we say so?" And how could this bill, kicked around back and forth as it was, up and down, both houses of Congress how could it be that nobody said, "Why, look, if we mean 'every time', let's just put it in"? It seems to me that is not the idea of a statesman; that is the idea of anybody who normally is in the legislative function; and the fact that it did not happen and that rested purely on prominence as opposed to "every time" in my judgment is clear from the face of the language itself.

Then Mr. O'Brien came along and he said, Well, I think I have a resolution for it. Let's make them do it the first time.

And they said, No, we don't like that idea. We think it is preferable to remain where it was in terms of prominence.

We have cited, your Honor, the specific language of the Managers, which I think appears at page 13 of our brief—

The Court: Mr. Gesell, before we get into the legislative history of this, may I digress a minute here.

I have listened to what you had to say on this particular section which is at issue, which is 502(e), I believe.

Mr. Gesell: They are both at issue, 502(e) and (n).

The Court: What is your interpretation of 502(n) with reference to the advertisement?

Mr. Gesell: It is the same.

The Court: In other words, that it is not required in the advertising?

Mr. Gesell: No. That is right.

[fol. 31] The Court: Or in the literature; for the established name to be prescribed but once and then half the size?

Mr. Gesell: I do not say but once, your Honor; I do not say but once. I say that the statute says—

The Court: It doesn't have to do it every time, doesn't have to be printed. All right.

Mr. Gesell: Every time. It must just be prominent. Mr. Goodrich says I say once, but I do not. It is up to this

agency to deal with the problem of prominence, but to say "every time" and to say that the statute requires the "every time" is where I believe they have exceeded their authority.

The Court: Well, under your argument where is there any authority for them to make a rule or regulation more than once?

Mr. Gesell: Well, I would suppose that under the rule-making power that they have, if they felt they wanted to give more meaning to a word, to the word "prominent", that they would be able to do that, as I think they have where that word has appeared in other sections of the Act.

The Court: You mean that if they did that, then that would be reasonable, but what they are doing here is unreasonable?

Mr. Gesell: No, no. But, see, then they would have to go through a rule-making process that they could support with logic and with findings and with facts under the Administrative Procedure Act. They have not done any of that. I don't say that one time is sufficient. It probably would be on many things. I would certainly think so on most one-page things and on most labels. Perhaps an issue would arise that if you got a book—

[fol. 32] The Court: Well, I could think of writing a paper four or five pages long and using it just once and never using the brand name again. If seems to me that if the drug people wanted to do that, that they confuse the doctor more than ever.

Mr. Gesell: Well, yes, because as they fell away from the brand name, then the doctor doesn't know what is involved. The suggestion that this trained group of people—and we are talking of prescription drugs, and the advertising, you realize, is in medical journals—has to have it every time in order to understand it, is like my saying to your Honor, or having some court say to both of us that in a brief like this every time I say "plaintiffs and defendants" I have to put a paren and list all these plaintiffs and de-

fendants each time so you are sure you know what I am talking about.

The Court: I might not read your brief.

Mr. Gesell: I think you might not. And I think the doctor may not read that. And of course, your Honor, we made specific allegations of that character which are not controverted here. There is no answer, there is no answering affidavit, that this was confusing, that it tended to detract from the individuality of the products, and all of those issues are here. But it is perfectly clear to me that Congress could not have had this concept in mind and not have said so.

Now, that is a simple statement, but I think that is the issue here. Could anyone have meant—a responsible group of men—we will assume they all had a high school education or better—could they have written a statute to mean "every time" and never said it?

[fol. 33] Now, I find it incredible to believe that the interpretation which is proposed here is what was intended, just as in our own practical knowledge and common sense—

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It means to me that you must look and give great weight to the statute. You then must give weight to the formal documents in terms of order, and it is only as you get way down this scale of legislative history as to what the Supreme Court Judges have said as to psychoanalyzing Congress that you are put into the question of trying to understand what Senator Kefauver meant in the statements to which we refer.

The Court: Well, don't you feel that what Senator Kefauver said was pretty obvious when he made his report?

Mr. Gesell: Yes, I think it is pretty obvious.

The Court: What the Senator had in mind.

Mr. Gesell: If we are talking about the same statement.

The Court: I am talking about the statement on page 20870, Section 112.

Mr. Gesell: Let me get that, your Honor. Yes, you are talking about the statement—

The Court: It is in your brief, too.

Mr. Gesell: Yes, at the top of page 12. Is that the one we are talking about?

The Court: I think so, yes. Let me just check this. Well, yes, but that does not state the whole thing. Let me read it for the record. It says in this section—this is Senator Kefauver speaking—Section 112: "Name to be used on drug labeling":

> [fol. 34] "In this section both the Senate and House versions were identical with one exception. This was a limitation upon the frequency with which the established name should appear in labeling, which among other things includes direct mail advertisements, brochures, pamphlets, and so forth; under the limitation the established name would have had to be printed only 'at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used.'"

Now, that is the O'Brien amendment he is talking about.

Mr. Gesell: Yes.

The Court: "This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth."

Mr. Gesell: Now, I didn't hear the words "every time".

The Court: Well, what am I reading here?

Mr. Gesell: I think you are reading the same thing I am reading. That is the closest you come and it has got the word "wherever" in it.

The Court: Well, all right. I am glad I read that over.

Mr. Gesell: And it is just what Mr. Eastland said when he said "if".

The Court: I think Mr. Goodrich brainwashed me pretty well because when I read that up here to myself I read into it "every time". I thought that is what Senator Kefauver had said. So I am glad I read that out loud.

[fol. 35] Mr. Gesell: I had not thought that he ever had said "every time". That is why I asked which statement you were referring to.

The Court: I looked through this rather hurriedly to see if anybody had ever said anything about "every time", and I didn't think it did until this morning when I read that and I was trying to listen to your argument, and I read "every time" into Senator Kefauver's words.

* * * * * * *

The Court: I don't know that we could go that far. I think that we would have to rely upon your expertise in this maybe to every piece of labeling that came along unless it was something that was practically—I mean, that everybody looked at and said, "Why, this is ridiculous."

Mr. Goodrich: But you would have the setting of a real case, your Honor, my point is, rather than here you are passing on—Mr. Gesell finally agrees with me—a multitude of promotional pieces that you have not seen. You are being asked to rule that we cannot require the "each time" without seeing how it might work, without seeing how the firms actually tried to comply, and if they did not comply, then there is no question of anybody going to jail or anything being seized, if we are wrong in our interpretation. But this is where these cases have been set for approval and for review.

Now, I think I must get to your other point of nobody ever saying "every time". Senator Kefauver said—

The Court: Let's get back to this final action business. I am not sure that you have answered me.

Mr. Goodrich: The regulation is a final interpretive regulation. It only becames a final operative regulation under the cases which we have cited when it is applied to a specific fact situation in an enforcement case.

[fol. 36] The Court: But isn't this final in the sense that nothing remains to be done except somebody disobey this and you make a recommendation to the Department of Justice to prosecute?

Mr. Goodrich: On a particular fact setting, yes, but the particular fact setting has to arise first. This is just like the Los Angeles case we cited—

The Court: Do you mean to say that in any case of controversy there always has to be a single action between civil plaintiffs and someone?

Mr. Goodrich: There has to be a concrete factual issue so that your judgment may take effect and be a final judgment as a matter of res judicata, settling rights between the parties, not just coming out with an advisory opinion on what the statute means in the abstract. This is my problem, that you are asked to come out with an interpretation of the statute which will be binding on us as an agency of the United States, binding on the Attorney General presumably if he ever wants to come out with an enforcement action.

The Court: Only insofar as if I were to say that you had exceeded the authority under the statute. If I do that, it leaves it to you to determine what new regulation you want to make.

Mr. Goodrich: I am glad you mentioned that.

The Court: Maybe you might be back in this same Court, or maybe if I did that, you would try to arrange some method to get out of this District and someplace else.

Mr. Goodrich: I am the defendant here, your Honor.

The Court: I know, but you might try.

[fol. 37] Mr. Goodrich: If it weren't for the honor of the thing, I would just as soon not be here, as Will Rogers once said.

The point I am making is there isn't any middle ground here.

You asked a very excellent question of Mr. Gesell and he answered it by referring to a non-existent statutory procedure. Where do we go from the "one time" to the "each time"? Where do we get the statutory authority to say it goes on each page or it goes on every fourth page or it goes at the top or it goes at the bottom? We considered all those things. We tried to arrive at what we thought the Con-

gress had in mind and when they said "wherever" we thought they meant everywhere. This is the normal meaning of the language used.

The Court: You don't mean to tell me that you looked at this statute as Mr. Gesell looked at it and said "This is too hard to say just where we should stop, so we will just make it every time."

Mr. Goodrich: No, we did not, your Honor. We went to actually what Congress had done. We tried to be true to the job we have in the executive branch to carry out what Congress said. Now, Congress took this very point up. It was not any problem of psychoanalysis. As I understand psychoanalysis, you are searching for some subconscious feeling that the patient does not know he has and you are trying to explain why he is sick on that basis. We don't have to look for subconscious expressions here or get a couch or any other thing. We simply have to look to what the Congress did in rejecting the amendment of Mr. O'Brien; what Senator Kefauver, speaking for the Senate conferees, said to the world. The conference committee was a closed meeting. He is the only one that explained exactly what happened there. Senator Kefauver is the father of this bill. You read this legislative history all the [fol. 38] way through and you come out with the feeling that everyone, including Senator Eastland, deferred to his understanding of what had happened in the conference report, and there we are. If you rule that we can't do it every time we would hope that you would tell us how to do it, and this is where our trouble is.

The Court: I can't do that.

Mr. Goodrich: What kind of judgment are we going to have then? If you are going to give us some legal advice we would appreciate that, but we don't think it can be a binding judgment.

The Court: I don't want to give you an advisory opinion.

Mr. Goodrich: Sir?

The Court: I don't want to give you an advisory opinion.

Mr. Goodrich: Well, if you rule against "every time"—we hope you will—we are going to have to know what the

thinking is that tells us that there is something in this statute between "one time" and "every time".

To get back to the prominence of the thing, the problem of the prominence was to be sure it was not sunk over in very small print. Some of these promotional pieces use newspaper-type print, which is eight point. Half the size would be four point and you would have to have your trifocals in order to see it, and the statute says prominently, but in type at least half as large.

When I go to the business of the declaratory judgment always authorizing this sort of an action, there aren't any cases on the books that tell us that. Mr. Gesell says that Larson is the authority. Larson is directly in our favor. [fol. 39] I request your Honor to read Adams and Nagle in it, which covers the very point he made.

On Storer, if I may be permitted—I know our time is getting late—

The Court: That is all right. You keep right on. I am asking you these questions and I have asked Mr. Gesell these questions in order to elicit all the aid I can.

Mr. Goodrich: I have argued enough cases, your Honor, to know that I get more good out of an argument when you ask me a question than if I talk all day, because this is the only way we can really communicate. So I appreciate the questions.

From Storer, however, there is a quote which says, "If the respondent could not rightfully seek a review from the order adopting the challenged regulations it must await action to its disadvantage under them. In the light of the legislation allowing review we hold that he has standing."

That is my point about those cases. There was a special provision in the Communications Act which authorized a suit before a three-judge court to enjoin the enforcement of regulations. This is now part of the Hobbs Act. I am sure you are familiar with it. There is nothing of that kind here. Where Congress provided review before the Court of Appeals they said so. They said so in this very statute under 502(n). This is the one on the advertising.

They allowed review of the regulations we established telling what would be in the advertisement in terms of effectiveness, side effects, and so forth. They did not make it applicable to this type of regulation. Nothing could show a stronger intention of the Congress.

When we took the Ewing v. Mytinger and Casselbury case to the Supreme Court the Court held that Congress [fol. 40] had done a selective job here of making some provisions reviewable and making others not reviewable.

They cited the Brotherhood case, which Congress precluded review by not providing for it in one place and by providing for it in another. This is cited in the Ewing v. Mytinger and Casselbury case

The main problem I do think that I must turn to is this point that Mr. Gesell makes so strongly and apparently impressed you that no one ever said "every time". If somebody meant it why didn't they say it? We take the position Kefauver said it not once, but said it in the committee report in August, said it again after Mr. O'Brien had tried to cut it back, and that we are simply faced with a practical problem here of how to administer this statute. If we don't go to "every time", Mr. Gesell's brief doesn't help us. He says that he does not mean only once. If you read his brief it says once on page 6, and when you get on over a little later he says that the limited presentation in the O'Brien amendment was not necessarily adequate. Now, where is the middle ground? We think that the Congress with its eyes wide open required every time. There is nothing wrong with every time.

You mentioned the situation of a medical article which might use the brand name only once. This is the usual situation in the papers in the American Medical Association Journals, for example. They are required to use the established name in discussing the drug, and the trade name might be in a footnote. Congress here did not want to do away with the trade name, but they provided that the established name should be used every time so that doctors could be educated to equivalency. We think that is what the statute means.

Thank you. Do you have any further questions?

[fol. 41] The Court: No, I think that is all. If I may I would like to ask Mr. Gesell one question.

Mr. Gesell: Yes, your Honor.

The Court: I must say, Mr. Gesell, when you got away from the use of the name once I was a little bit surprised. Just as a practical matter, have you got any idea how the Department could administer this Act if it does not mean just once or every time?

Mr. Gesell: Yes, your Honor, and what I would like to do is, if I may, say this: That I have not explored this matter with all of my clients and I am speaking purely personally now and I don't know the view of all these different companies. But it is perfectly apparent to me that there is a middle ground. I think Mr. Goodrich is asking you to give him the advisory opinion, not I.

The Court: I don't have the authority, but I thought from the argument you might be able to give it to me.

Mr. Gesell: Well, one can conceive of coming at it in terms of having to be once on every page of multi-page documents. One can come with the view that if the trade name were used in the title of some kind of publication this should also be in the title. There are ways short of every time. You have no idea what this does to a piece of literature. It is just as though—I do not mean to be sacrilegious, your Honor—one read the Bible and one always defined who the Lord was every time the Lord's name appears in the document. It absolutely will drive physicians, companies, readers, and everyone else to distraction. There are certain ways that intelligent people could work it out. We have indicated to Mr. Goodrich a willingness to sit down and try to work it out with him, but we are not going to take lying down the notion that we have to do it his way when Congress didn't tell him that.

[fol. 42] The Court: Do you mind if I let Mr. Goodrich answer you?

Mr. Gesell: No, no, your Honor.

Mr. Goodrich: I must simply say, your Honor, that in order for you to pass on the validity of what Mr. Gesell

has just said here you will have to look at the promotional pieces. This is why we think it is so essential that the application of this regulation await the actual presentation of promotional pieces.

Now, I had a group of them organized to bring here. Mr. Gesell's people did not particularly want to present it at this time. I deferred and presented the case on this basis, but I cannot emphasize too strongly that the actual operation of this statute cannot be passed on in the abstract by any such idea that it will ruin the promotional piece to use the generic name.

The Court: Sir, you don't have the manpower, do you, to go over every piece of promotional literature? There has got to be some way that some rules and regulations which are apparent to you and also reasonably clear to the industry without—

Mr. Goodrich: We think our regulations are clear.

The Court: There is no question about your regulation now that it is perfectly clear, but there has got to be some clarification of this thing. I don't think I have to get into the practicality of this matter, but, nevertheless, I always like to know the practical side of it. But I don't think that this Court has to look at every piece of literature any more than you do to determine whether or not this statute and what you have done is beyond the authority given you by the statute. All I am saying is you just like to know what the practical effect is going to be.

[fol. 43] Mr. Gesell: May I point out, your Honor, in this informal discussion, that this enforcement regulation runs equally to every type of piece of paper across the board. Mr. Goodrich is talking about looking at these pieces of paper. His enforcement regulation treats of everything identically.

Mr. Goodrich: We do recall from the establishment of "each time" we think that is what Congress required. We think the reviewability of that type regulation does not apply in this sort of suit for declaratory judgment.

[fol. 44]

IN THE UNITED STATES DISTRICT COURT

OPINION—April 30, 1964

WRIGHT, *Chief Judge.*

This action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. § 301, et seq. ("the Act").

According to § 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), the labeling of a prescription drug shall cause that drug to be "misbranded" unless the established or generic name of the drug is printed prominently on any label or labeling material, as defined in the Act, in type half as large as any brand or proprietary name.[1]

The proprietary, or brand name, of a prescription drug is used by the manufacturer to identify the source of the drug. The proprietary name distinguishes the drug manufactured by one company from the drug with active ingredients of the same or similar chemical constitution produced by another company. Thus a physician can, if he desires, exercise a choice among sources in prescribing drugs for his patient.

Most prescription drugs also have a non-proprietary or generic name. Such a name may be a systematic chemical name, a common name, or an official name used in some official compendium or designated by the Secretary of Health, Education and Welfare. This is the "established name" which § 502(e)(1)(B) requires to be prominently displayed on drug labeling. If this requirement is not met and a misbranded drug is introduced into interstate commerce (a) the drugs may be seized and forfeited, (b) the introduction of such drugs into interstate commerce may be enjoined, (c) the persons who cause introduction of the

[1] The language of § 502(n) of the Act, 21 U. S. C. § 352(n) which applies to advertising is similar. This opinion covers both sections although only § 502(e) is specifically discussed.

misbranded drugs into interstate commerce may be subject to criminal prosecution.

[fol. 45] In February, 1963, the defendant, Commissioner of Food and Drugs proposed the adoption of certain new regulations under the Act. The final regulations, 28 Fed. Reg. 6375, were promulgated in June, 1963 and were effective on publication. It is these regulations which are under attack in the present proceeding. Under the new regulations the Act is interpreted to require that the established or generic name be placed in conjunction with every appearance of the proprietary name of the drug on labels and advertising.

Thirty-seven drug companies and the Pharmaceutical Manufacturers Association (PMA) have joined as plaintiffs to challenge the every time requirement. They claim that the statute does not direct or authorize the defendant Commissioner to impose the requirement and that the Commissioner's regulations are therefore null and void. They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it. This material, including brochures, price lists, catalogues and labels prominently sets forth the generic name of the prescription drug involved but it does not meet the every time requirement.

At the outset, a host of jurisdictional problems are presented.

I. *Venue.*

The defendants, Secretary of Health, Education and Welfare and Commissioner of Food and Drugs claim that venue is improper as to twenty-six of the thirty-seven plaintiff corporations. These twenty-six are not incorporated in the State of Delaware.

[fol. 46] The applicable venue statute, 28 U. S. C. 1391(e) reads:

> "A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

Defendants admit that the pharmaceutical companies incorporated in Delaware are residents of Delaware within 28 U. S. C. 1391(e)(4). They maintain that the other plaintiffs fall without the bounds of the venue provision because they do not reside in the forum state.

28 U. S. C. 1391(e) does not define residence as applied to corporations. Elsewhere in the venue statute, however, at 28 U. S. C. 1391(c) it is provided:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes."

Plaintiffs argue that this broad definition of residence should be applied to the twenty-six contested parties. Defendant counters that 28 U. S. C. 1391(c) applies only to corporations appearing as defendants and not to plaintiff

corporations because it refers only to corporations which "may be sued."

The interpretation of 28 U. S. C. 1391(c) presents no novel question. There is a classic split of authority among the federal courts as to whether the statute applies to defendant corporations only or to plaintiff and defendant [fol. 47] corporations alike.[2] Nor do the commentators find ground for agreement.[3]

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[2] Defendant corporations only:

Chicago & North Western Ry. Co. v. Davenport, 94 F. Supp. 83 (S. D. Iowa 1950); United Merchants & Manufacturers Inc. v. United States, 123 F. Supp. 435 (M. D. Ga. 1954) [Dicta]; Albright & Friel, Inc. of Delaware v. United States, 142 F. Supp. 607 (E. D. Pa. 1956); Nebraska-Iowa Bridge Corporation v. United States, 158 F. Supp. 796 (D. Neb. 1958); Robert E. Lee & Co. v. Veatch, 301 F. 2d 434 (4 Cir. 1961) cert. den. 371 U. S. 813 (1962).

Plaintiff and defendant corporations:

Freiday v. Cowdin, 83 F. Supp. 516 (S. D. N. Y. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N. D. Ohio 1952); Southern Paperboard Corporation v. United States, 127 F. Supp. 649 (S. D. N. Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426 (E. D. Pa. 1956); Standard Insurance Company v. Isbell, 143 F. Supp. 910 (E. D. Tex. 1956); Travelers Insurance Company v. Williams, 164 F. Supp. 566 (W. D. N. C. 1958) aff'd 265 F. 2d 531 (4 Cir. 1959); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); Consolidated Sun Ray, Inc. v. Steel Insurance Company of America, 190 F. Supp. 171 (E. D. Pa. 1961).

[3] Defendant corporations only:

1 Moore, Federal Practice 1503 (2d ed. 1950); Ohlinger's Federal Practice (Rev. ed.), Vol. 1-A, p. 297; Comment, "The Corporate Plaintiff and Venue under Section 1391(c) of the Judicial Code, 28 Univ. Chi. L. Rev. 112 (1960); Case note, 48 Va. L. Rev. 968 (1962).

Plaintiff and defendant corporations:

Wright, Federal Courts, § 42 (1963); Wechsler, Federal Jurisdiction and the Revision of the Judicial Code, 13 Law & Contemporary Problems 216, 240 note 126; Note, The Proposed Revision of the Federal Judicial Code, 60 Harv. L. Rev. 424 (1947); Case note, 76 Harv. L. Rev. 641 (1963); 1 Barron and Holtzoff, Federal Practice and Procedure, 387-88 (Rev. ed. 1960) citing note, Federal Venue and the Corporate Plaintiff: Judicial Code § 1391(c); 28 Ind. L. J. 256 (1953) and note, Federal Venue and the Corporate Plaintiff, 37 Ind. L. J. 363 (1962).

Those courts which conclude that 28 U. S. C. 1391(c) redefined the law of corporate residence for corporations as plaintiffs as well as corporations as defendants rely on interpretation of the last words of the section, "and such judicial district shall be regarded as the residence of such corporation for venue purposes." These words, it is argued, would be superfluous unless applied to corporations as plaintiffs, for the first part of the section grants the right to sue corporations as defendants where they are incorporated, or licensed to do business, or are actually doing business.

[fol. 48] Judge Dimock's statement is representative:

> "I do not feel at liberty to attribute to Congress any * * * tautology. The statute first gives permission to sue a corporation in any district where it is incorporated or licensed or doing business. It then declares that such district shall be regarded as its residence. No one has suggested any reason for that declaration unless it was to give permission to the corporation to sue others in such district in addition to the previously given permission given to others to sue the corporation in any such district." Southern Paperboard Corporation v. United States, 127 F. Supp. 649, 650 (S. D. N. Y. 1955).

Professor Moore has found a meaning for the disputed words which does not comport with the above.

> "The language of the first clause of subsection (c) restricts the subsection to a corporation which 'may be sued.' And this restriction does not make superfluous the second, and concluding clause that 'such judicial district [in which the corporation is incorporated or licensed to do business or is doing business] shall be regarded as the residence of such corporation for venue purposes.' This clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing

in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state. * * *" 1 Moore, Federal Practice 1503 (2d ed. 1963).

Nonetheless, Moore does not place his chief reliance on this interpretation in deciding that the statute defines residence for corporate defendants only. He emphasizes the fact that the Reviser's Note fails to indicate any intention to effect what would be a far-reaching change as to residence of corporate plaintiffs.

[fol. 49] This position is seconded in the recent opinion, Robert E. Lee & Co., Inc. v. Veatch, 301 F. 2d 434 (4 Cir. 1961), cert. den. 371 U. S. 813 (1962). There the court concluded that Congress would have designed a more sweeping language for Section 1391(c), such as using "all corporations" in the second clause "instead of the restrictive term 'such corporation'", if Congress had intended to do more than codify the rule of Neirbo Co. v. Bethlehem Shipbuilding Corp., Ltd., 308 U. S. 165 (1939), [that a corporation waives its venue privilege not to be sued in a state by obtaining a license to do business there].

Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court. This court is persuaded by those who argue that Congress did not intend the sweeping change which plaintiffs assert and that for purposes of 28 U. S. C. 1391(c) residence is defined only for corporate defendants. The court also holds that the residence of a corporation for purposes of 28 U. S. C. 1391(e) is defined in Section 1391(c). The twenty-six corporations which are not incorporated in Delaware are not properly before the court as plaintiffs in the present action.

II. *The PMA and Standing to Sue.*

The next jurisdictional objection raised by the defendants concerns the standing to sue of the PMA. It is asserted that there is no actual controversy between PMA and the defendants. The regulations promulgated by the Commissioner do not apply to the Association; it neither manufactures nor distributes drugs and it has no occasion, therefore, to either label drug products or advertise them.

The PMA claims to be harmed in a strict dollars and cents fashion by the disputed regulations. The Association points out that under Article III of its by-laws membership dues are based on the annual business of its members. [fol. 50] Rules which affect the income of its members therefore affect PMA.

It is not in its own right, however, but as the representative of some 140 drug companies that this court finds PMA to have standing to sue. In National Motor Freight Traffic Association, Inc. v. United States, certain associations of motor carriers sought to set aside a decision of the Interstate Commerce Commission. The Government argued that the plaintiffs lacked standing to sue because they were associations of carriers rather than the carriers actually affected by the contested order. The lower court agreed with the Government's contention holding that the associations were not qualified to sue because they suffered no legally cognizable injury "except in the remote sense that the problems of their members are their concern." National Motor Freight Traffic Association, Inc. v. United States, 205 F. Supp. 592, 593 (D. C. 1962), aff'd 372 U. S. 246 (1963).

The Supreme Court specifically rejected this ground for decision:

> "The appellants are associations of motor carriers, authorized under 49 USC § 5b, and perform significant functions in the administration of the Interstate Commerce Act, including the representation of member carriers in proceedings before the Commission. Since

individual member carriers of appellants will be aggrieved by the Commission's order, and since appellants are proper representatives of the interests of their members, appellants have standing to challenge the validity of the Commission's order in the District Court." National Motor Freight Traffic Association, Inc. v. United States, 372 U. S. 246, 247 (1963).

The defendants here make much of the Supreme Court's reference to the authorization of motor carrier associations under 49 U. S. C. § 5b. That section, however, does no more than insulate associations approved by the I. C. C. [fol. 51] from violation of the antitrust laws. The crux of the opinion centers on the association as a representative of members who are individually harmed. In that sense, the PMA is similar to the associations in the Motor Freight Traffic case. It represents its members before the Food and Drug administration just as the motor carrier associations appeared in their members' behalf before the I. C. C.

The PMA is a proper representative of the interests of its member drug companies and has standing to challenge the validity of the defendant Commissioner's regulations in this Court.

III. *Propriety of a Judicial Determination at This Time.*

Next the defendants put forward two related arguments which go to the propriety of adjudication at this stage in the proceedings. First, they say that there is no actual controversy between the plaintiffs and defendants as required by the Declaratory Judgment Act, 28 U. S. C. § 2201.[4] Second, they maintain that regulations interpretive in nature, are reviewable only as they may later be

[4] Plaintiffs also claim to be here under § 10 of the Administrative Procedure Act, 5 U. S. C. A. § 1009. Since the court finds that they are properly here for a declaratory judgment it is not necessary to discuss the procedure for review of administrative rule making.

called into question in an enforcement action and not upon their promulgation.

If a regulation is final and a justiciable controversy exists as to its legality, the regulation is ripe for review. A justiciable controversy arises where a plaintiff is confronted with substantial present or imminent harm. The regulations before the court are final and a justiciable controversy exists. The very presence of a threat of harm makes the regulations ready for review. Davis, Administrative Law Treatise, § 21.07.

Defendants say that plaintiffs should not be permitted a declaratory judgment but should have to await an enforcement proceeding before they can call the contested regulations into question. Plaintiffs may have judicial [fol. 52] review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. Frozen Food Express v. United States, 351 U. S. 40 (1956); Federal Trade Commission v. Nash-Finch Company, 288 F. 2d 407 (D. C. Cir. 1961). They need not await an action which would only make the threat of harm more pressing. The possibility of harm is already apparent to this court. The regulations in issue have placed them in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution. It is of no moment that the Attorney General and not the Food and Drug Administration may enforce these rules. Nor does it matter that the Attorney General has not yet threatened enforcement. Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means. From the plaintiffs' point of view danger is imminent. The regulations of which they complain are ripe for review. The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril. To bar the courts to plaintiffs would be to do an injustice.

IV. *The Attorney General as an Indispensable Party.*

The defendants next argue that the action cannot proceed because an indispensable party, the Attorney General, has not been joined. They point out that proceedings to enforce the Act or to restrain violations of the Act are to be brought in the name of the United States and that it is the Attorney General in his discretion who is granted authority to bring actions enforcing the Act.

Going back to first principles, indispensable parties are persons who have such an interest in a controversy that a final decree cannot be concluded without affecting that interest. 3 Moore, Federal Practice, 2156 (2d ed. 1963). [fol. 53] It would seem unnecessarily cumbersome to hold that the Attorney General is such a party here. The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides. It is the defendants upon whom the benefit or blight of this decision will fall. The decree will expend itself on the defendants and not the Attorney General. The Attorney General is not a party indispensable to the instant litigation. See Federal Trade Commission v. Nash-Finch Company, supra.

V. *The Present Controversy as an Unconsented Suit Against the United States.*

Finally, defendants argue that this litigation is an unconsented suit against the United States.

The point out that the doctrine of sovereign immunity intervenes where the relief sought would interfere with the public administration or restrain the Government from acting or compel it to act. One of the cases cited in accord with this proposition is Larson v. Domestic and Foreign Commerce Corp., 337 U. S. 682 (1949). However, in Larson a significant exception is noted:

> "There may be, of course, suits for specific relief against officers of the sovereign which are not suits

against the sovereign. * * * [W]here the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden. His actions are 'ultra vires' his authority and therefore may be made the object of specific relief. It is important to note that in such cases the relief can be granted, without impleading the sovereign, only because of the officer's lack of delegated power." Larson v. Domestic and Foreign Commerce Corp., Ibid. at 689-90.

[fol. 54] In their complaint plaintiffs assert:

"20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. * * *"

The relief plaintiffs seek is a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.

This court does not regard plaintiffs' claim that defendants have acted outside the scope of their authority as frivolous. As the Larson case notes, a suit challenging the unauthorized actions of government officials is not a suit against the United States. This action may go forward in the absence of the United States consent to be sued. See, Philadelphia Company v. Stimson, 223 U. S. 605 (1912).

The decision of the merits of this case does not require as lengthy discussion as does negotiation of the procedural maze leading to the merits. The proposition is simple: Congress has enacted legislation setting out rules which

must be complied with if a drug is to be properly branded. The Commissioner of Food and Drugs has issued regulations interpreting the Act of Congress. Plaintiffs attack these regulations.

Regulations of the type with which the court is here concerned are valid unless unreasonable or inconsistent with the statute. Davis, Administrative Law Treatise, § 5.05 (1958). The statute and the disputed regulation are here set out.

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

[fol. 55] "(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

"Section 1.104(g), 28 Fed. Reg. 6375 (June 20, 1963):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

[fol. 56] "(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

It is clear from the legislative history that the chief concern of Congress in enacting § 502(e) was the prominent display on labeling of the generic name of a drug. Congress intended to put an end to the previous common practice whereby drug companies would mention the generic name of a drug in an inconspicuous place in microscopic print in order to enhance the value of their own trade name. Congress took pains to assure that the generic name would be printed in type large enough to be seen. This was accomplished by specifying that the generic name be printed in type at least half as large as that used for the trade name.

Not only was Congress concerned with the size of the display of the generic name, it was also concerned with the position of that display. To that end, Congress re-

quired that the generic name be placed "prominently" on labeling. This was the concern of Congress. It is necessarily the concern of the court.

Congress did not specify what it meant by prominent display. Would one mention of the generic name in juxtaposition with the first mention of the trade name suffice? In printed matter comprising several pages should the generic name be mentioned on each page at least once, perhaps at the top of the page? Congress laid down no guide lines.

The defendant Commissioner has interpreted the language of Congress with a broad sweep. He says that the generic name must appear at every mention of the trade [fol. 57] name. His interpretation is inconsistent with the statute. The very word which he has seized on to support the every time requirement belies the argument that Congress intended the generic name be used every time. If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word "prominently". The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary.

The defendants maintain that the legislative history indicates the adoption by Congress of the every time requirement. They rely heavily upon a statement by Senator Kefauver in which the Senator explained the Conference Committee's rejection of an amendment offered by Congressman O'Brien in the House. The O'Brien amendment would have required that the generic name appear "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

Kefauver explained,

"This limitation was not accepted by the conferees. Thus the established name of a prescription drug must

appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962).

First, it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate. Second, Kefauver's term "wherever" is not free from ambiguity. It could mean that the generic name must appear each time the trade name is mentioned, On the other hand, it could mean that the generic name must appear on a label or brochure or medicine box wherever the trade name is used. Apparently Kefauver favored the every time requirement. [fol. 58] But nowhere in the legislative history is there evidence to show that other members of the Congress favored the every time requirement or that they were aware that "prominently" should have a special meaning.

The views of Senator Kefauver, in this instance, cannot override what the court believes is the general Congressional intent. This is especially true since the expression of those views are circumscribed and open to doubt.

If Congress had meant that the generic name should appear with every mention of the trade name, it could have said so. It has not. It has said only that the generic name must appear prominently. The st ute will not bear the interpretation which the defendants have put upon it.

Submit order in accordance herewith.

Wilmington, Delaware
April 30, 1964

[fol. 59]

IN THE UNITED STATES DISTRICT COURT

UNITED STATES DICTRICT COURT
DISTRICT OF DELAWARE
WILMINGTON 1

Chambers of
CALEB M. WRIGHT
Chief Judge

May 19, 1964

Alexander L. Nichols, Esq.
Morris, Nichols, Arsht & Tunnell
du Pont Building
Wilmington, Delaware 19801

Alexander Greenfeld, Esquire
United States Attorney
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v. Celebrezze, C. A. 2737

Gentlemen:

I have read the proposed orders submitted by plaintiffs and defendants. The only difference of substance is that the third paragraph of the proposed order submitted by plaintiffs is not included in the proposed order submitted by the Government.

I see no reason to require counsel to meet with me with respect to the form of order which I propose to sign. I will give parties one week for the plaintiffs to submit their reasons for insisting upon the inclusion of paragraph 3 in said order as submitted by them, and the same period of time for the defendants to make known their insistence that said paragraph be excluded from the proposed order.

Very sincerely yours,

CALEB M. WRIGHT,
Chief Judge.

CMW:pcg
cc—Edward G. Pollard, Clerk

[fol. 60]

IN THE UNITED STATES DISTRICT COURT

Letterhead of

COVINGTON & BURLING
Union Trust Building
Washington 5, D. C.

REpublic 7-5900

May 26, 1964

Hon. Caleb M. Wright
Chief Judge
United States District Court
for the District of Delaware
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v.
Celebrezze, et al., C. A. 2737

Dear Judge Wright:

This letter, in response to Your Honor's letter of May 19, 1964, sets forth the plaintiffs' reasons for maintaining that the judgment to be entered should contain an injunction, as provided for in paragraph 3 of their proposed form of order, against the defendants' enforcement of the regulations which have been found to be invalid.

The Complaint in this action requested both a declaratory judgment and injunctive relief. (Complaint, p. 15). In the Court's opinion of April 30, 1964, Your Honor characterized the relief requested by the plaintiffs and the nature of the action as follows (pp. 4-5):

> "[The plaintiffs] . . . claim that the statute does not direct or authorize the defendant Commissioner to impose the [every time] requirement and that the Commissioner's regulations are therefore null and void.

> They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the [fol. 61] disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it."

The plaintiffs' Motion for Summary Judgment was not limited to only a part of the relief requested in the Complaint, and we believe that plaintiffs are entitled to a judgment for all of the requested relief, in view of the Court's opinion holding the regulations reviewable and invalid.

It is wholly appropriate for the judgment to contain both a declaration of the regulations' invalidity and an injunction against their enforcement. As Professor Moore points out,

> "The declaratory action offers both an alternative and cumulative remedy, not an exclusive one. . . . Hence a prayer for coercive relief may properly be combined with a prayer for a declaratory judgment; and the judgment on the merits may likewise combine both remedies, and couple, with a declaratory judgment, injunctive relief. . . ." 6 Moore, *Federal Practice* 3047 (2d ed. 1953). (Footnotes omitted.)

In suits to review actions of administrative agencies, the same "ripeness" standard is applicable whether the suit is one for a declaratory judgment or for an injunction. 3 Davis, *Administrative Law* 312 (1938). Thus, the Court having determined that the regulations at issue in this case were ripe for review, the elements necessary for the entry of an injunction have already been found by the Court.

Basically, the injunction is required to afford the successful plaintiffs the protection, to which they believe they

are entitled under the Court's decision, from possible action by FDA personnel inconsistent with the Court's declaration of the regulations invalidity, whether in administrative [fol. 62] proceedings before the agency or in connection with a seizure or other type of enforcement measure.

The plaintiff companies and the other members of the Pharmaceutical Manufacturers Association, as a continuing matter, are constantly required to deal with personnel at all levels of the Food and Drug Administration on such matters as the labeling for drugs and the contents of package inserts and other labeling or advertising materials. The inclusion of the injunction as prayed for in the Complaint is the logical and proper method of insuring that there will be uniform recognition by all of the agency's personnel that no efforts, formal or informal, should be made to enforce these regulations which have been determined by this Court to be invalid and beyond the agency's authority. This is particularly necessary because of the large number of FDA personnel who have responsibilities relating to labeling and advertising, and the various ways in which they deal with these matters.

Including an injunction in the Court's order is the only way to insure that its judgment will be effective. In this connection, we refer to *National Hairdressers' & C. Ass'n* v. *Philad Co.*, 41 F. Supp. 701 (D. Del. 1941), an opinion written by Judge Biggs which was affirmed *per curiam* by the Third Circuit. 129 F. 2d 1020 (3d Cir. 1942). The action there was by an alleged infringer of a patent for a declaration of the patent's invalidity and for an injunction against infringement suits by the patent owner. The Court held the patent invalid, and then determined that an injunction should also issue:

> "The relief granted to [plaintiff] . . . and those on whose behalf his suit was brought should be completely effective and obviate the necessity or possibility of suits by [defendant] . . . against members of the class

represented by [plaintiff] . . . based upon alleged infringement of [the patent held to be invalid] . . . " 41 F. Supp. at 708.

[fol. 63] The reasoning of Judge Biggs was made more explicit in his opinion on a motion for rehearing:

"Assuming that a patent is held to be invalid . . . in a declaratory judgment suit, . . . the owner of the patent can still maintain infringement suits in other jurisdictions. As a defense the plaintiff in the declaratory judgment suit . . . can maintain a plea of res adjudicata in bar of the action. In the light of this fact, in the case at bar, in order to avoid a multiplicity of infringement suits against the members of [plaintiff's] . . . class, in each of which the defendant could maintain a plea of res adjudicata, it is proper to grant injunctive relief." 41 F. Supp. at 709.

The only difference between that case and the present one is that here the defendants are officers of the Federal Government. However, the principles governing the relief to which a successful plaintiff is entitled are the same whether the defendant is a private party or a Federal officer. 6 Moore, *Federal Practice* ¶ 56.26[3] (2d ed. 1953). This is especially true here, where the regulations have been held invalid, since there is no *proper* governmental interest which would be affected by an injunction against the regulations' enforcement.

We respectfully submit that the inclusion of the requested injunction is the desirable way of informing the defendants and all persons under their authority that, under penalty of contempt, they may not attempt to enforce the invalid regulations.

Respectfully yours,

Gerhard A. Gesell.

cc: Alexander Greenfeld, Esq.
William W. Goodrich, Esq.

pc

[fol. 64]

IN THE UNITED STATES DISTRICT COURT

May 28, 1964

Honorable Caleb M. Wright
Judge, United States District Court
District of Delaware
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v. Celebrezze, et al.—Civil Action No. 2737.

Dear Judge Wright:

Mr. Goodrich has communicated with our office and has asked us to indicate to you that the Order which the Government has submitted in the above-captioned matter deletes any provision relating to an injunction for the following two reasons:

"(1) The opinion of April 30, 1964 said nothing about an injunction. Instead it indicated to us that the Plaintiffs were entitled to relief in the form of 'a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.' (p. 19).

(2) The Court has held that this is not a suit to restrain the Government from acting or compel it to act. A sweeping injunction against not only the officers who have acted 'ultra vires' but also against all employees of the Department of Health, Education, and Welfare and the Food and Drug Administration would be inconsistent with the idea that this is not a suit against the United States."

[fol. 65] If we can be of any further assistance to you in this matter, please let us know.

Sincerely,

ALEXANDER GREENFELD,
United States Attorney.

By: WILLIAM J. WIER, JR.,
Assistant United States Attorney.

WJW:mjl

[fol. 66]

IN THE UNITED STATES DISTRICT COURT

JUDGMENT—June 1, 1964

This cause having come on to be heard upon the Complaint and Motions of the respective parties, and the matter having been briefed and argued by counsel for the respective parties and maturely considered by the Court, and the Court having filed herein its Opinion dated April 30, 1964, thereupon, in conformity with said Opinion.

IT IS, this 1 day of June, 1964 HEREBY DECLARED, ADJUDGED AND ORDERED by the Court as follows:

(1) That plaintiffs, American Home Products Corporation, Baxter Laboratories, Inc., Cutter Laboratories, The Dow Chemical Company, Chas. Pfizer & Co., Inc., Philips Roxane, Inc., G. D. Searle & Co., Sterling Drug Inc., The Upjohn Company, Vale Chemical Company, Inc., Warner-Lambert Pharmaceutical Company, and Pharmaceutical Manufacturers Association (as representative of its member companies), have standing to sue in this Court for the relief prayed in this action, and their Motion for Summary Judgment is granted.

(2) That Sections 1.104(g)(1) and 1.105(b)(1) of the General Regulations for the Enforcement of the Federal Food, Drug and Cosmetic Act, 28 Fed. Reg. 6375 (June 20,

1963), issued by the defendant Commissioner of Food and Drugs acting under authority delegated to him by the defendant Secretary of Health, Education and Welfare, insofar as these sections require that the established name of a prescription drug must accompany each appearance of such drug's proprietary name or designation, are null and void and of no effect, and the statutory provisions on which they are based do not impose, or authorize the defendants to impose, the requirements which they embody.

[fol. 67] (3) That the defendants and each of them, and all persons acting under their direction and authority, or in active concert or participation with them, are hereby perpetually enjoined and restrained from enforcing or causing to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding, the requirements of said regulations enumerated in paragraph (2) hereof.

(4) That defendants' Motion to Dismiss and for Summary Judgment is denied as to the plaintiffs named in paragraph (1) hereof.

(5) That the Complaint is dismissed without prejudice as to the remaining plaintiffs for lack of proper venue.

(6) That the respective parties shall bear their own costs of this action.

Caleb M. Wright, *C. J.*

Approved as to Form:

Morris, Nichols, Arsht & Tunnell, Alexander L. Nichols, William S. Megonigal, Jr., *Attorneys for Plaintiffs.*

Attorneys for Defendants.

[fol. 68]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15054

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES, Appellants.

Appeal From the United States District Court for the District of Delaware.

Argued April 2, 1965

Before HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

[fol. 69]

OPINION OF THE COURT—Filed November 1, 1965

PER CURIAM.

The named appellants in the above entitled case are some, but not all, of the plaintiffs who joined in the complaint for declaratory judgment and injunctive relief.

We find no prejudicial error in the dismissal of the complaint as to these plaintiffs, and that action will be affirmed.

[fol. 70]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15,054

[Title omitted]

On Appeal From the United States District Court for the District of Delaware.

Present: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT—November 1, 1965

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that paragraph five of the judgment of the District Court, filed June 1, 1964, be and the same is hereby affirmed.

Attest:

Ida O. Creskoff, Clerk.

[File endorsement omitted]

[fol. 71]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15055

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS, Appellants.

Appeal From the United States District Court for the District of Delaware.

Argued April 2, 1965

Before: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT—Filed November 1, 1965

By WEBER, *District Judge*

This is an appeal from a declaratory judgment and injunction granted to plaintiffs in the District Court which holds that regulations issued and promulgated by defendants, the Secretary of Health, Education and Welfare, and the Commissioner of Food and Drugs are null and void and not authorized by the statute on which they are based. The injunction restrains the defendants and all parties acting under them from enforcing or attempting to enforce the regulations.

[fol. 72] The statute involved is popularly known as the "Drug Amendments of 1962", which added the provisions in question to the Federal Food, Drug and Cosmetic Act, as amended. 21 U.S.C. § 301 et seq. (The Act).

§ 502 (e)(1)(B) of the Act, 21 U.S.C. 352 (e)(1)(B) provided that the labeling of a prescription drug shall be considered "misbranded" unless the established or generic name of the drug is printed prominently on the label in type half as large as any brand or proprietary name. § 502 (n) of the Act contains a similar requirement for advertising matter concerning the drug. Penalties are provided for "misbranding."

The generic name or the established name of a drug is its chemical name, a common name, or an official name used in an official compendium. The proprietary name is the name given by the manufacturer to designate its source of manufacture and to differentiate its product from the same or chemically similar drugs from other manufacturers.

§ 502 (e)(1)(B), 21 U.S.C. 352 (e)(1)(B) contains a provision that to the extent that compliance with the requirements is impracticable, exceptions shall be established by regulations promulgated by the Secretary.

§ 701 (a), 21 U.S.C. 371 (a) grants the authority to the Secretary to promulgate regulations for the efficient enforcement of the Act, except as otherwise provided in that section.

§ 701 (e)(1) of the Act provides the procedure to be employed for the issuance, amendment, or repeal of any regulations under specific sections of the Act, including the filing and disposition of objections thereto by full hearing, the issuance of final orders thereon by the Secretary, and the provision for appeal thereon to the Circuit Court of Appeals. The sections of the Act in question here were not covered by the hearing appeal process recited above.

Pursuant to the authority to promulgate regulations, the Commissioner, as the delegate of the Secretary, issued the [fol. 73] regulations in question here, which provided that under the provisions of § 502 (e)(1)(B), (the labeling requirement), and § 502 (n), (the advertising requirement) of the Act, *each time* the trade name is used on labels or labeling, or in advertisements of prescription drugs, the established name shall also be used prominently and in type half as large. (21 C.F.R. 1.104 (g)(1) and 1.105 (b)(1); 28 Fed. Reg. 6375 and 6376). These regulations were adopted in accordance with the procedure provided by § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, after publication of notice of intent, and the submission of comments and objections by interested parties.

Plaintiffs brought this action in the District Court praying for declaratory judgment and injunctive relief. They rely on the existence of a Federal question, 28 U.S.C. 1331, the Declaratory Judgment Act, 28 U.S.C. 2201, and § 10 of the Administrative Procedure Act, 5 U.S.C. 1009 for jurisdiction. They contend that the *each time* requirements of the regulations are invalid as beyond the requirements of the Act.

The District Court found it unnecessary to rule whether § 10 of the Administrative Procedure Act provided a basis for review of the regulations. It took cognizance of the case under the Declaratory Judgment Act on the grounds that the regulations placed plaintiffs in a position of peril and imminent danger, and that the regulations in question were ripe for review. It not only declared the regulations void because the statute would not bear the interpretation placed upon it, but also issued a sweeping injunction against the enforcement thereof.

Questions of venue of the District Court for all of the many plaintiffs, the standing of a trade association as a party, the inclusion of the Attorney General as a necessary party, and the status of the case as an unconsented suit against the United States were disposed of by the Court, and by reason of the conclusions reached herein, will not be discussed.

[fol. 74] The basic question on appeal here is one of justiciability. May the district court review, under the Declaratory Judgment Act, an interpretive regulation of the Commission issued under authority of the statute, where Congress has not provided for judicial review of the sections in question? Furthermore, was such review within the statutory scheme of regulation imposed by Congress when it specifically provided for judicial review of other regulations authorized under certain specific sections of the Act, as set forth in § 10 (e)(1), 21 U.S.C. 371? We believe that the answer would be the same under the provisions of § 10 of the Administrative Procedure Act, which imposes essentially the same requirements for justiciability as the Declaratory Judgment Act.

A District Court of the United States is limited to those cases over which Congress has granted it jurisdiction. To a large extent the provisions for judicial review of administrative agency action are not applicable to the District Courts, but are placed under the jurisdiction of the Courts of Appeal. Those cases arising from the District Courts which review administrative regulations are largely based on statutory provisions for such review. *Frozen Food Express Co.* v. *United States*, 351 U. S. 40 (1956), was reviewed under the statutory scheme for review of I.C.C. orders by a specially constituted District Court, 28 U.S.C. 1336. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942) arose under § 402 (a) of the Communications Act of 1934, 47 U.S.C. § 402 (a), which provided for judicial review of certain orders of the Federal Communications Commission by a specially constituted District Court, with direct appeal therefrom to the Supreme Court. Under § 402 (b) of that Act review of other types of orders are available only through an appeal to the Court of Appeals of the District of Columbia.

It seems clear to this Court that the intent of Congress was that the administrative regulations for which no review was specifically provided prior to enforcement were those [fol. 75] interpretive regulations which represented the

Commissioner's interpretation of the meaning of the Act. The regulations in question are not those having the force and effect of law by virtue of authority delegated by the Act; they are not an "adjudication" and they are not an "order" and "licensing" under the definitions of § 2 (d) of the Administrative Procedure Act, 5 U.S.C. 1001 (d), as a standard for determination of final agency action as required for judicial review under § 10 of that Act.

The regulations in question were adopted pursuant to § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, which provided for a hearing on the proposed rules before their promulgation. In such a case, the intent of Congress as shown by the specific review provisions of the Act, 21 U.S.C. 371 (e), was to preclude judicial review prior to the enforcement stage. It may be noted that in § 502 (e)(1)(B), Congress has provided for exemption regulations for the labeling requirements where compliance is impracticable. No attempt has been made by plaintiffs to secure relief under that provision.

It has been frequently held that judicial review of such preliminary administrative determination does not fit the statutory scheme of Congress. As was stated in *Ewing* v. *Mytinger & Casselberry*, 339 U. S. 594 (1950), at pp. 600-601:

> "Congress made numerous administrative determinations under the Act[1] reviewable by the Courts.[2] But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided for in the libel suit. Cf. *Switchmen's Union* v. *Board*, 320 U.S. 297, 305-306."

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[1] The Act in question here.

[2] Footnote omitted.

[fol. 76] As has been recently stated by the Supreme Court in *Whitney National Bank* v. *Bank of New Orleans*, 379 U. S. 411 (1965) at p. 420:

> "Congress has set out in the Bank Holding Company Act of 1956 a carefully planned and comprehensive method for challenging Board determinations. That action by Congress was designed to permit an agency, expert in banking matters, to explore and pass on the ramifications of a proposed bank holding company arrangement. To permit a district court to make the initial determination of a plan's propriety would substantially decrease the effectiveness of the statutory design."

and at page 422:

> "That Congress has not expressly provided that the statutory procedure is to be exclusive does not require a different conclusion."

In addition to the policy of Congress in limiting the administrative matters for which judicial review was provided, which did not include the sections of the Act in question, there are serious obstacles to the use of the Declaratory Judgment Act here as a basis of jurisdiction.

> "A declaratory judgment, like other forms of equitable relief, should be granted only as a matter of judicial discretion, exercised in the public interest. *Brillhart* v. *Excess Insurance Co.*, 316 U. S. 491; *Great Lakes Dredge & Dock Co.* v. *Huffman*, 319 U. S. 293, 297-98; H.R. Rep. No. 1264, 73rd Cong. 2d Sess. p. 2; Borchard, Declaratory Judgments (2d ed. 1941) pp. 312-14. It is always the duty of a court of equity to strike a proper balance between the needs of the plaintiff and the consequences of giving the desired relief. Especially where government action is involved, courts [fol. 77] should not intervene unless the need for

equitable relief is clear, not remote or speculative." *Eccles* v. *Peoples Bank*, 333 U. S. 426, at p. 431 (1948).

The regulations in question are advisory statements as opposed to legislative rules. Cf. *Standard Scale Co.* v. *Farrell*, 249 U. S. 571 (1919). The Act does not give them the force of law, they rise no higher than the terms of the Act itself.

The Declaratory Judgment Act confines the remedy to be limited to an actual "case or controversy". There must be proof of threatened enforcement action that would cause irreparable harm; the judgment sought must conclusively settle a specific controversy between the parties. *Public Service Comm'n* v. *Wycoff*, 344 U. S. 237 (1952).

The case must be appropriate for judicial determination. The relief is available only for a "concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged . . . ." *Aetna Life Insurance Co.* v. *Haworth*, 300 U. S. 227, 241 (1937).

In the case in question the district court was asked for an advisory opinion rather than a concrete decision. It was asked to substitute its discretion for an administrative discretion as to the meaning of the Act. No specific case was presented, no immediate prosecution threatened. The administrative intention was expressed but had not yet come to fruition.

> "The judicial power does not extend to the determination of abstract questions. *Muskrat* v. *United States*, 219 U. S. 346, 361; *Liberty Warehouse Co.* v. *Grannis*, 273 U. S. 70, 74; *Willing* v. *Chicago Auditorium Assn.*, 277 U. S. 274, 289; *Nashville, C. & St. L. Ry Co.* v. *Wallace*, 288 U. S. 249, 262, 264." *Ashwander* v. *Tennessee Valley Authority*, 297 U. S. 288, at p. 324 (1936)

The threat of enforcement must be real, and not merely implied by the existence of the law and regulations. This [fol. 78] would require the exercise of administrative dis-

cretion by the agency and also by the Attorney General. There was no threat of enforcement facing the plaintiffs here sufficient to give an adequate basis for declaratory relief. *United Public Workers* v. *Mitchell*, 330 U.S. 75, (1946).

Perhaps, the closest parallel to the instant case is *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (D. C. Cir. 1943), which involved an administrative interpretation of a section of the same Act by the Commissioner. The Court details the stages of exercise of discretion between an administrative interpretation and prosecution. The Court concluded at p. 683:

> "We conclude that the present case was not an appropriate one for declaratory judgment . . . The Supreme Court has said the pronouncements, policies and programs of a government administrative agency do not give rise to a justiciable controversy, save as they have fruition in action of a definite and concrete character, constituting an actual or threatened interference with the rights of persons complaining." (citing *Ashwander* v. *T.V.A.*, supra).

The jurisdiction of the District Court in this case is likewise limited by equitable principles that such relief as is demanded here is available only in the absence of an adequate remedy at law. *Beacon Theatres* v. *Westover*, 359 U. S. 500, (1958), *Douglas* v. *Jeannette*, 319 U. S. 157 (1943). Congress has provided a variety of avenues of legal remedy; the exemption provision in the statute where compliance is impracticable, the opportunity to be heard in the rule making proceedings of § 4 of the Administrative Procedure Act; the opportunity to test the interpretation under the enforcement procedures provided for "misbranding", which are (1) seizure proceedings, (2) injunction proceedings, or (3) criminal prosecution. § 301 (a) and (b), 21 U.S.C. 331 (a) and (b). Likewise, if enforcement should be attempted under the new drug clearance pro- [fol. 79] cedures of § 505, 21 U.S.C. 355, or the antibiotic

certification, § 507, 21 U.S.C. 357, there are provisions for administrative hearing and review by the Court of Appeals. Ultimately, final recourse to the District Court for relief under the Declaratory Judgment Act or the Administrative Procedure Act, § 10 in a concrete factual setting involving an actual controversy, is not ruled out at a later stage in the administrative process.

We, therefore, hold that in view of the policy of Congress limiting prior judicial review of administrative actions under this Act to specific sections, not including the ones in question, and in view of the absence of an "actual case or controversy" required for justiciability under the Declaratory Judgment Act, the action of the district court was beyond its permissible area of discretion and the judgment must be vacated, the injunction dissolved, and the action dismissed.

An appropriate order will be entered.

[fol. 80]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15,055

[Title omitted]

On appeal from the United States District Court for the District of Delaware.

Present: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT—November 1, 1965

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the District

Court, filed June 1, 1964, except as to paragraph five, be, and the same is hereby vacated, the injunction dissolved, and the cause remanded to the District Court with directions to dismiss the complaint in accordance with the opinion of this Court.

Attest:

Ida O. Creskoff, Clerk.

[File endorsement omitted]

[fol. 81] Clerk's Certificate to foregoing transcript (omitted in printing).

[fol. 82]

SUPREME COURT OF THE UNITED STATES

No. 824, October Term, 1965

ABBOTT LABORATORIES, ET AL., Petitioners,

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ORDER ALLOWING CERTIORARI—February 28, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Third Circuit is granted, and the case is placed on the summary calendar.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.